



Gemelli trio-smart® breath test

COMMERCIALIZING REVOLUTIONARY BREATH TEST TECHNOLOGY

Gemelli is a privately owned biotechnology company that specializes in diagnostics related to conditions in the microbiome. Gemelli is commercializing a breath test called trio-smart® based on technology licensed from Cedars-Sinai's [MAST program](#). The **trio-smart® breath test** measures the levels of hydrogen, methane, and hydrogen sulfide in the breath of patients after lactulose or glucose consumption. The levels of measured gases help identify bacterial overgrowth and other GI illnesses.

CHALLENGE

Update the licensed prototype developed at Cedars into the next generation of prototype for use in a Clinical Laboratory Improvements Amendment (CLIA) certified laboratory. The updated instrument is being used to run samples as a Laboratory Developed Test (LDT). An LDT is an in vitro diagnostic test manufactured by and used within a single laboratory which is subject to regulatory oversight by the FDA in the US.



PROCESS

Cedars and StarFish worked on the initial prototype together to prove out aspects of the core technology and clinical validity. Gemelli met StarFish through Cedars and built a great relationship with Mark Drlik, StarFish Medical Director of Program Design, and many other key members of the StarFish team. A 2018 working session with StarFish solidified the project goals.

The team worked with Dr. Mark Pimentel's laboratory to test samples using the prototype and a new proprietary collection system that collected early and meaningful clinical data to build confidence in the solution. The collection system captures and transports all three gases (hydrogen, methane, and hydrogen sulfide) using sealed bags. The collection system is optimized for breath sample collection and sample transportation to the Gemelli laboratory.

The StarFish and Gemelli teams utilized that prototype and then developed the commercial instruments that sit within a CLIA certified laboratory in California. This design cycle leveraged StarFish Medical's royalty free Data Acquisition system to accelerate development and included StarFish experts in a wide variety of engineering disciplines to take the key elements from an early prototype to a purpose-built, integrated device that could be validated within the laboratory setting.

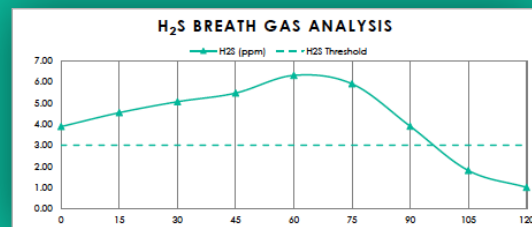
Consistency between instruments remained an important requirement as a large number of instruments are required to have sufficient capacity in the CLIA certified laboratory. The instruments can be calibrated by lab personnel on a daily basis. No matter where the breath is coming from, or which machine it goes to, there is consistency between all of the different instruments.

"StarFish Medical is pleased to be a part of Gemelli's ongoing success in transforming the SIBO and IBS testing and diagnostic market by offering something that's quite revolutionary in this space, that allows a lot of underserved folks to finally get real answers about their GI symptoms."

"With Gemelli's strong clinical and strategic understandings in the area, the developed technologies are now having a positive impact on the quality of life for patients suffering from SIBO and other microbiome illnesses"

> Mark Drlik
Director of Program Design
StarFish Medical





TEAMWORK

Matt Mitcho, CEO, Gemelli Biotech:

"StarFish has been a great partner working across a number of different project partners, including our laboratory. They helped with the development of the instrument and assisted us in making sure that the collection system is top notch. Now they are working with us as we service the instruments and monitor their wear and tear so there is consistency in results across all of the instruments."

"We've worked really closely with the StarFish team in order to proactively send an instrument back for factory calibration and to make sure we're assessing all of the different components of each instrument to keep them operating without interruption within the commercial setting. That relationship is the most important between StarFish and our CLIA Laboratory."

"I highly recommend working with someone like StarFish, specifically to develop this type of asset because we don't have the engineering or supply chain expertise in-house. We eventually could or will, but at the stage that we were in three years ago, it was definitely a great opportunity for outsourcing and even ensuring the scalability of the products. We did look for outside partners to take the plans in order to develop additional instruments cheaper. We came right back to StarFish because of the relationship that we've built and the reliability of the end product, which in the end is what allows us to service the customers that trust us with their testing."

"The process that StarFish goes through to ensure that the instruments that we've developed are top notch, calibrated perfectly, and can provide consistent results over time can be tedious, but is never cumbersome. That process has given us confidence to enter the market. It has also given our CLIA certified laboratory confidence that the instruments that they are working with are really unmatched because of the gauntlet that we've gone through in order to ensure their consistency, efficiency, and effectiveness."

RESULTS

"We ended up in a really good place over time by developing a couple of instruments up front in order to allow us to get to market. When we needed to build additional capacity ahead of the influx of samples that we're seeing now, we were able to work with the same team that developed not only the initial Cedars prototype, but our prototypes and our first few instruments that we're using commercially."

An ordering prescriber within the US can go and set up an account at triosmartbreath.com, our website. A lot of gastroenterologists, naturopathic physicians and primary care professionals are using our tests. The best way to see whether this is working is to not only gauge if patients are satisfied, but to also determine if providers are happy.

With this type of disease category, we read out levels of gases that are associated with symptoms and then a patient takes either a therapeutic or dietary intervention of some sort. To learn how they're doing with the treatment, they assess themselves through a doctor's order using our instrument.

We've had a ton of great feedback, not only from patients, but from providers who continue to order. It's great working with our customer base and hearing the feedback on the consistency of the results that they're experiencing and their willingness to use the trio-smart® breath test for additional patients. That's how we assess whether or not it's working.

The consistency of employment at StarFish is something that we put a lot of value in. Mark Drlik has been our primary contact, but there are a variety of folks that have been working on our projects or program for a number of years. We believe in taking a step forward, assessing, learning and then making things better. Now we're in the process of moving past the initial design in order to go to a next generation instrument that will allow for greater throughput, quicker results with better software, and the same level of quality that we're experiencing currently. We're doing all of that with StarFish. We're not looking to go somewhere else because of the relationship that we have and the success that we've had together.

I appreciate the opportunity to share our story and to hopefully connect with folks in the industry or lay people that are suffering that we could potentially help."

trio-smart® Provides a More Complete Fermented Gas Profile of the Microbiome

The trio-smart breath test measures the levels of hydrogen, methane, and – for the first time - hydrogen sulfide in the breath of patients after lactulose or glucose consumption.

trio-smart aids in the identification of small intestinal bacterial overgrowth (SIBO), intestinal methanogenic overgrowth (IMO) and excess hydrogen sulfide.

Using best-in-class breath testing technology, trio-smart is the only clinical breath test to measure all three of the primary fermented gases in the microbiome.

To learn more, visit:

[triosmartbreath.com >](https://triosmartbreath.com)

Visit starfishmedical.com/tools for more medical device commercialization tools.

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